

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 recites the limitation "the ballasting means" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10, 17-23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lointier *et al.*, hereinafter referenced as "Lointier" (PCT Application Publication Number WO 03/055420 A1) in view of Knowlton (United States Patent Number 6,427,089).

Lointier discloses an expandable intragastric balloon (1) comprising a first pouch (20) with a port (4), a second pouch (2) with a hole (4') which contains the first pouch, and a sealing member (5) fastened onto the second pouch in a leak-proof manner. The pouches are assembled together with the aid of a fastening element (10A) inside a passage defined by a neck by exerting force on the neck to pinch it between the sealing

member and the fastening element (see second fastening element 3'). While Lointier discloses the balloons being made of silicon, he fails to disclose the pouches being made of different, non-compatible materials. Knowlton discloses that an outer balloon which contacts the stomach wall can be made of a non-compliant material, such as polyurethane (col. 8, lines 37-47). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the outer balloon of Lointier with the polyurethane material disclosed by Knowlton in order to provide a predictable balloon diameter.

Regarding claim 2, Lointier discloses the sealing member and the second pouch being connected by gluing (paragraph [0054]).

Regarding claim 3, Lointier discloses a flange (11) enabling the sealing member to be fastened to the hole by adhesive.

Regarding claim 4, Lointier discloses a septum (see spacer of 10A between flanges 11) inside the passage, substantially opposite the flange.

Regarding claim 5, Lointier discloses the fastening element ensuring leak tightness. While this may involve only minimal compression of the sealing member and septum, it is still sufficient to prevent leaking.

Regarding claim 6, the neck extends from the port inwards towards the interior of the first pouch (see Figure 3).

Regarding claim 7, the neck comprises an internal wall (21) defining a passage, and the fastening element (10A) is arranged to surround the neck and to exert pressure

on it such that the neck conforms in shape substantially to the sealing member in a leak-proof manner.

Regarding claim 8, the fastening element of Lointier comprises a ring (spacers between ref. 11 are ring-shaped).

Regarding claim 10, Lointier discloses an elastomer valve (paragraph [0058]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the valve of a silicone elastomer, similar to the material used for the pouch, in order to provide a more cost-effective production process by using the same material for multiple components.

Regarding claim 17, Lointier discloses manufacturing a flexible intragastric balloon via steps comprising manufacturing at least one first pouch with a port, assembling the first pouch with a second pouch with a hole, manufacturing a sealing member to seal the port and hole, fastening the sealing member onto the second pouch in a leak-proof manner (see discussion of claim 1 above). Lai discloses sealing a port or hole by mounting a sealing member inside a passage defined by a neck extending from the port of the first pouch and fastening the sealing member onto the first pouch with a suitable fastening element by pinching the neck between a sealing member and a fastening element (see discussion of claim 7 above).

Regarding claims 21-22, the sealing member of Lointier comprises a flange which is glued to the periphery of the hole (paragraph [0054]).

Regarding claim 23, Lointier discloses a septum arranged inside the passage substantially opposite the fastening element (see spacer of 10A between flanges 11).

Regarding claim 25, Lointier discloses the flange being glued about the periphery of the hole (paragraph [0054]).

Claims 11-16 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lointier in view of Knowlton, as applied to claims 1 and 17 above, and further in view of Paganon *et al.*, hereinafter referenced as “Paganon” (PCT Publication Number WO 2005/039457).

While Lointier and Knowlton fail to disclose a ballasting means, Paganon discloses an intragastric balloon (1) with a ballasting means (3). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the ballasting means of Paganon in the modified invention of Lointier and Knowlton in order to provide a means of weighting the balloon and improving its position in the stomach (abstract).

Regarding claims 12-13, Paganon discloses ballasting means comprising several solid bodies connected by wires with spacers between them (paragraphs [0055] – [0059]).

Regarding claims 14-15 and 24, Paganon discloses the ballasting means being supported by and attached to the fastening element via the valve (paragraph [0060]).

Regarding claim 16, Paganon discloses the ballasting means being housed inside a first pouch (paragraph [0048]).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRIAN GRAHAM whose telephone number is (571)270-7484. The examiner can normally be reached on Monday - Friday 8:00 am-5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/B.J.G./
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/Todd E Manahan/
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